

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
HAMMOND DIVISION**

BARBARA KAISER and)	
ANTON KAISER,)	
)	
Plaintiffs,)	
)	CAUSE NO. 2:17-CV-114-PPS
v.)	
)	
JOHNSON & JOHNSON and)	
ETHICON INC.,)	
)	
Defendants.)	

OPINION AND ORDER

On November 28, 2017, I heard oral argument on Ethicon's four Motions for Final Ruling on Outstanding *Daubert* Issues. DE 249, 253, 257, 258. At the oral argument, the Parties informed me that, in light of my rulings on Plaintiffs' *Motion in Limine* to Exclude FDA 510(k) Evidence, DE 244, and Ethicon's Motion to Admit FDA Evidence, DE 248, the Plaintiffs, Barbara and Anton Kaiser, agreed that they will not be calling Peggy Pence, Ph.D. to testify at trial. The Parties also informed me that they agreed that Dr. Uwe Klinge will not be testifying as to the topics on which Ethicon sought to exclude his testimony. I, therefore, denied as moot, Ethicon's motions for final ruling as to Peggy Pence, Ph.D. and Prof. Dr. Med. Uwe Klinge. [DE 274.]

That leaves two of the Kaisers' experts for my consideration: Dr. Iakovlev and Dr. Elliott. As for Dr. Iakovlev, I indicated at oral argument, and confirmed in a subsequent Order, that Ethicon's Motion for Final Ruling as to Dr. Vladimir Iakovlev, DE 258, was conditionally granted and he would be prohibited from testifying

regarding one of his opinions. I told the parties that I would put my reasons in writing, and this is that opinion. As for Dr. Elliott, after hearing the Parties' argument regarding the admissibility of some of his opinions it was clear to me that I needed additional briefing to resolve the issues. I have now received that briefing.

Let's start with the basics. The admissibility of expert testimony is governed by Federal Rule of Evidence 702 and the Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 (1993). See *Lewis v. Citgo Petroleum Corp.*, 561 F.3d 698, 705 (7th Cir. 2009). Rule 702 provides, in relevant part, that if "scientific, technical or other specialized knowledge will help the trier of fact[,] . . . a witness who is qualified as an expert by knowledge, skill, experience, training or education may testify thereto in the form of an opinion" Fed. R. Evid. 702. The Rule "also requires that: (1) the testimony must be based upon sufficient facts or data; (2) it must be the product of reliable principles and methods; and (3) the witness must have applied the principles and methods reliably to the facts of the case." *Happel v. Walmart Stores, Inc.*, 602 F.3d 820, 824 (7th Cir. 2010).

Under this framework, this Court must act as a gatekeeper for expert testimony, determining prior to admission whether the testimony is both relevant and reliable. *U.S. v. Pansier*, 576 F.3d 726, 737 (7th Cir. 2009). In conducting this inquiry, the Court is to focus solely on principles and methodology, not on the conclusions that they generate. *Winters v. Fru-Con Inc.*, 498 F.3d 734, 742 (7th Cir. 2007). "The goal of *Daubert* is to assure that experts employ the same 'intellectual rigor' in their courtroom

testimony as would be employed by an expert in the relevant field.” *Jenkins v. Bartlett*, 487 F.3d 482, 489 (7th Cir. 2007) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)).

I will begin with Dr. Iakovlev. Dr. Iakovlev is a clinical pathologist designated by the Kaisers to provide general expert opinions about the Prolift product. Ethicon sought to exclude Dr. Iakovlev’s opinion that Prolene, Ethicon’s proprietary blend of polypropylene, antioxidants, and other additives used in its mesh products, degrades *in vivo* based on his “degradation bark theory.” [DE 256.] Here’s how Ethicon characterizes that particular opinion of Dr. Iakovlev:

Dr. Iakovlev uses histological stains on pathology specimens containing Prolene mesh. After staining, Dr. Iakovlev examines the specimens using a light microscopy, and observes a “bark” that he believes consists of degraded Prolene polypropylene.

[*Id.* at 2-3 (citations omitted).] Ethicon argues that “[t]his theory has no basis in any scientific literature or theories, and is wholly unreliable.” [*Id.*]

Dr. Iakovlev’s “bark” theory was first brought to the attention of Judge Joseph Goodwin, the judge overseeing this massive MDL. Judge Goodwin found, and Ethicon does not appear to contest, that Dr. Iakovlev’s testimony on degradation, generally, is supported with reference to scientific literature and internal Ethicon documents and is admissible. The present issue is whether Dr. Iakovlev’s manner of corroborating the scientific literature by performing his own tests is reliable or not.

An expert's opinion must be the product of reliable principles and methods. *Happel v. Walmart Stores, Inc.*, 602 F.3d 820, 824 (7th Cir. 2010). "The Supreme Court has identified the following factors as pertinent to this inquiry: (1) whether the theory has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error; and (4) whether it has been generally accepted within the relevant scientific community." *Id.* (citing *Daubert*, 509 U.S. at 593). "[T]he courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it." *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996)

When the issue was first raised before Judge Goodwin, he found that he had "insufficient evidence to evaluate the methodology Dr. Iakovlev actually employed to examine mesh samples that allegedly degraded *in vivo*" and reserved ruling on this issue until Dr. Iakovlev's methodology could be examined firsthand at trial. [DE 258-3 at 8.] At the time that Judge Goodwin took up this issue, it appeared that Dr. Iakovlev was running tests to support his methodology, but they had not yet been completed. [See DE 264-4 at 10-11; DE 258-2 at 5-7.] So the matter was deferred by Judge Goodwin so that Dr. Iakovlev's tests could be finished.

The case was remanded to me for trial, and Ethicon has now re-raised the issue of the admissibility of Dr. Iakovlev's "degradation bark theory." Ethicon contends that it remains unsupported. In their cursory, two sentence response, the Kaisers unhelpfully refer me to their briefing filed a year and a half earlier in the MDL Court, when Dr. Iakovlev had not completed his testing. [DE 264 at 2.] That briefing is

effectively useless to me in addressing the issue identified by Judge Goodwin—that there is “insufficient evidence to evaluate the methodology.” When I asked the Kaisers’ counsel at oral argument on the *Daubert* motions whether anything had changed, he conceded that Dr. Elliott hasn’t “presented any new evidence that would substantiate his methodology.” [DE 276 at 116-117.]

As such, there is no evidence before me to demonstrate that Dr. Iakovlev’s “degradation bark theory” is the product of reliable principles and methods. Testing on his theory has not been completed, it has not been subjected to peer review or publication, the rate of error is unknown, and it has not been generally accepted within the relevant scientific community. There simply isn’t enough evidence that Dr. Iakovlev’s thesis is supported by reliable principles and methods to allow him to testify regarding his “degradation bark theory.” It is for these reasons that Ethicon’s motion, DE 256, is granted. Dr. Iakovlev will be permitted to testify regarding his degradation opinions generally, but may not rely on his “degradation bark theory” as support for his opinions.

Next I turn to Dr. Daniel Elliott. Dr. Elliott is a pelvic surgeon and urogynecologist designated by the Kaisers to provide general expert opinions about Prolift. Ethicon originally sought to exclude several of Dr. Elliott’s opinions: (1) that nonsynthetic mesh procedures are a safer alternative for the surgical treatment of stress urinary incontinence; (2) that other synthetic mesh devices offer a safer alternative; (3) the adequacy of Ethicon’s research and testing; (4) alleged complications from the

Prolift procedure; and (5) certain product warning opinions. [DE 252.] The third and fourth issues were agreed to by the Parties at the oral argument, and therefore, were denied as moot. As to the third issue, the Parties agreed that Dr. Elliott only would testify regarding clinical studies and clinical trials and would not testify about biocompatibility testing or durability testing. [See DE 276 at 140-142.] As to the fourth issue, the Parties agreed that Dr. Elliott would not testify regarding potential complications from Prolift from which Mrs. Kaiser did not suffer. [*Id.* at 142-14.] The fifth issue also was agreed to at the oral argument. The Parties agreed that Dr. Elliott will testify regarding the risks associated with Prolift and whether those risks appeared in the relevant IFU, but he will not testify about what else potentially should have been included in the IFU. [*Id.* at 144-146.] This issue, therefore, is also denied as moot.

That leaves for my consideration the first two opinions of Dr. Elliott, both of which relate generally to whether there were safer alternative designs to the Prolift product. But before considering these two opinions, there is a predicate question to be answered: Is proof of a safer alternative design a necessary element of a design defect claim under Indiana law? The parties disagree on this fundamental point—Ethicon believes that it is a required element and the Kaisers argue that, while evidence of a safer alternative design is admissible to prove negligence, it is not required to produce such evidence. At the oral argument, I asked the parties to brief the issue which they have now done. I will address this issue first before turning to Dr. Elliott's specific opinions on the topic.

The Parties are in agreement that a negligence standard applies to design defect claims under the Indiana Products Liability Act. Specifically, the IPLA provides, “in an action based on an alleged design defect in the product or based on an alleged failure to provide adequate warnings or instructions regarding the use of the product, the party making the claim must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances in designing the product or in providing the warnings or instructions.” Ind. Code. § 34-20-2-2. But the IPLA did not always provide for a cause of action for negligent design defect.

Some background on the IPLA is necessary to fully understand how this issue has developed under Indiana law. In 1978, the Indiana Legislature enacted the IPLA. At the time, the IPLA provided that it “govern[s] all products liability actions, including those in which the theory of liability is negligence or strict liability in tort; provided however, that this chapter does not apply to actions arising from or based upon any alleged breach of warranty.” Ind. Code § 33-1-1.5-1 (1978). While the IPLA codified most aspects of the Restatement (Second) on Torts § 402A regarding strict liability, it spoke nothing of the treatment of actions sounding in negligence. As a result, the IPLA left claims based on negligence to the common law. See *Corbin v. Coleco Industries, Inc.*, 748 F.2d 411, 416–17 (7th Cir. 1984) (discussing the history of the IPLA). In 1983, the IPLA was amended, removing the reference to negligence actions, presumably recognizing the confusion that was created by the Indiana Legislature in 1978. See Ind. Code § 33-1-1.5-1 (1983) (“[T]his chapter governs all actions in which the theory of

liability is strict liability in tort.”); *Miller v. Todd*, 551 N.E.2d 1139, 1143 (Ind. 1990) (discussing the history of the IPLA); *Moore v. Sitzmark Corp.*, 555 N.E.2d 1305, 1308 (Ind. App. 1990) (“[A]n action [for negligent design] is not subject to the terms of the Indiana Product Liability Act; rather, it is a common law action.”).

In 1995, the IPLA was amended yet again. The idea was to bring all product liability actions under one umbrella. The 1995 version specifically applies to “all actions brought by a user or consumer against a manufacturer or seller for physical harm caused by a product regardless of the substantive legal theory or theories upon which the action is brought.” *See* Ind. Code § 33-1-1.5-1 (1995); P.L. 278-1995, Sec. 1 (effective July 1, 1995). The 1995 amendments brought some much needed clarity to product liability cases in Indiana by eliminating strict liability claims for all design defect and failure to warn claims and instead imposing a negligence standard in all such cases. It did so by adding the “reasonable care” language, quoted above, that remains in effect today. *See* Ind. Code § 33-1-1.5-3 (1995); P.L. 278-1995, Sec. 1 (effective July 1, 1995). In 1998, the IPLA was amended once more, but this amendment did nothing more than move the IPLA to Title 34. *See* Ind. Code §§ 34-20-1-1 to 34-20-9-1.

What this history shows us is that, until 1995, the standard for product liability claims sounding in negligence was established by the common law. During that time, the Courts held that, under Indiana law, a plaintiff “must offer a safer, more practicable product design than the design in question” to succeed on a negligent design defect claim. *Whitted v. General Motors Corp.*, 58 F.3d 1200, 1206 (7th Cir. 1995) (citing *Miller v.*

Todd, 551 N.E.2d 1139, 1143 (Ind. 1990)). Therefore, until July 1, 1995, a plaintiff was required to show that a safer alternative design to succeed on a negligent design defect claim.

I cite to *Whitted* for this explanation quite intentionally. It was decided on June 29, 1995, *before* the 1995 amendments establishing the negligence standard for design defect and failure to warn cases went into effect. Yet *Whitted*, or in a few circumstances its contemporaries or progeny, is the case relied upon in most of the authority on which Ethicon relies for its assertion that proof of safer alternative design continues to be a required element of a negligent design defect claim. *See, e.g., Simmon s v. Philips Elec. N. Am. Corp.*, No. 2:12-CV-39-TLS, 2015 WL 1418772 (N.D. Ind. Mar. 27, 2015) (quoting *Whitted*); *Hathaway v. Cintas Corp. Serv. Inc.*, 903 F. Sup.. 2d 669, 675 (N.D. Ind. 2012) (quoting *Whitted*); *McClellon v. Thermo King Corp.*, 2013 WL 6571946, at *10 (S.D. Ind. 2013) (quoting *Whitted* and citing *Barnard v. Saturn Corp., a Div. of General Motors Corp.*, 790 N.E.2d 1023, 1032 (Ind. App. 2003), which relies on a 1989 Indiana Court of Appeals case applying the old statute); *Hartman v. EBSCO Industries, Inc.*, 2013 WL 5460296, at *7 (N.D. Ind. 2013) (quoting *Rodefer v. Hill's Pet Nutrition, Inc.*, No. IP 01-123-C H/K, 2003 WL 23096486, at *9 (S.D. Ind. Nov. 7, 2003), which cites *Whitted*). In fact, it appears that all of the authority cited by Ethicon in support of its argument that a safer alternative design is a *prima facie* element of a negligent design defect claim traces back to pre-1995 amendment to the IPLA.

Admittedly, the Indiana Legislature was not particularly clear in 1995 regarding whether it intended to completely do away with the safer alternative design requirement. As a result, many federal and state courts in Indiana held course and continued to require it as an element of a plaintiff's negligent design defect claim. But matters changed in 2010 when the Indiana Supreme Court finally addressed the issue. In *TRW Vehicle Safety Systems, Inc. v. Moore*, 936 N.E.2d 201 (Ind. 2010), the plaintiff brought a negligent design defect claim, among others, against the defendant seatbelt manufacturer, TRW, and the defendant vehicle manufacturer, Ford, after the plaintiff's decedent was ejected through the sunroof of his vehicle when his seatbelt developed slack in a rollover that followed a tire failure. *TRW Vehicle Safety Systems, Inc.*, 936 N.E.2d at 208. The jury apportioned 5% of the fault to TRW and 31% of the fault to Ford. *Id.* The Court of Appeals reversed, finding insufficient evidence to support the jury's verdict. *Id.* The Indiana Supreme Court disagreed.

Ford and TRW argued that the evidence presented at trial was insufficient because it failed to establish the requisite standard of care and prove that their conduct fell below that. *Id.* at 208-209. Specifically, they argued that plaintiff failed to present evidence of the proper standard of care, to offer testing, data, studies, or other evidence to show a safer, more practicable product design, and to rebut evidence that its proposed alternative design itself presented safety concerns. *Id.* at 209. In response, the Indiana Supreme Court explained:

The Indiana Product Liability Act generally imposes strict liability for physical harm caused by a product in an unreasonably dangerous defective condition. Ind. Code § 34-20-2-1. For actions based on an alleged product design defect, however, the Act departs from strict liability and specifies a different standard of proof: '[T]he party making the claim must establish that the manufacturer or seller failed to exercise reasonable care under the circumstances in designing the product.' Ind. Code § 34-20-2-2. Thus the statute itself prescribes the applicable standard of care. We decline to require proof of any additional or more particular standard of care in product liability actions alleging a design defect.

Id. at 9. The opinion included a footnote at the end of the last sentence that reads:

The American Law Institute recommends a different approach, prescribing specific sub-elements of a claim for strict product liability based on design defect. It views a product as 'defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe.' Restatement (Third) of Torts: Products Liability § 2(b) (1997). Our legislature did not adopt this analytical framework but instead enacted in 1998 a negligence standard for product liability claims based on defective design. *See* Ind. Code § 34-20-2-2.

Id. at 209 n.2. The Indiana Supreme Court, therefore, plainly held that proof of alternative design is not required under Indiana law. It may, however, be probative evidence of the defendant's use of reasonable care. *Id.* at 209.

One would think that *TRW* put to bed the question of whether, under Indiana law, a safer alternative design is a necessary element of a design defect claim. But in the eight years that followed that decision, many state and federal courts in Indiana

continued to find that proof of alternative design is required for a design defect claim, citing to *Whitted* or its progeny in support of that assertion. These courts are, therefore, relying on outdated common law, which was superseded by the negligence standard spelled out in the 1995 amendments to the IPLA as confirmed by the Indiana Supreme Court in *TRW*. My job as a district judge sitting in a diversity case is to apply the law as the highest court of the state has announced it. See *State Farm Mut. Auto. Ins. Co. v. Pate*, 275 F.3d 666, 669 (7th Cir. ,2001 (“[A] United States district court sitting in diversity must apply the law of the state as it believes the highest court of the state would apply it if the issue were presently before that tribunal.” (internal citation omitted))). And the Indiana Supreme Court could not have been any clearer in *TRW* in holding that proof of an safer alternative design is not required under the IPLA. As the Indiana Supreme Court correctly pointed out in *TRW*, the Indiana Legislature could have adopted the standard set out in the Restatement (requiring proof of safer alternative design), but it chose not to. *TRW Vehicle Safety Systems, Inc.*, 936 N.E.2d at 209 n.2. It has not chosen to amend that language to add in a safer alternative design requirement in the eight years since the Indiana Supreme Court decided *TRW*.

What nails the point home that proof of a safer alternative design is not required under Indiana law is the fact that the Indiana Model Civil Jury Instructions do not say a single thing that suggests that proof of a safer alternative design is an element of a negligence product liability claim. See Indiana Model Civil Jury Instruction 2305. One would think that if proof of a safer alternative design was required in Indiana design

defect cases, the Indiana Model Civil Jury Instructions would reflect that fact. Yet they don't say boo about it.

Other courts have read *TRW* in the same way as I do. In *Hammons v. Ethicon, Inc. et al.*, No. 1305003913, 2016 WL 6821815 (Pa. Com. Pl. Sept. 30, 2016), a case involving an Indiana woman implanted with Ethicon's Prolift device, the Court of Common Pleas of Pennsylvania held that proof of an alternative design is not a required element under Indiana law. Citing and quoting *TRW*, that court ultimately held that, under Indiana law, "[t]estimony of an alternative design can be probative evidence as to the issue of the defendant's failure to use reasonable care and can support a reasonable inference of negligent design but is not requirement." *Hammons*, 2016 WL 6821815 at *5.

Likewise, in *Bailey v. Cottrell, Inc.*, 721 S.E.2d 571 (Ga. Ct. App. 2011) a Georgia case interpreting Indiana law, the court held that Indiana specifically has rejected a risk utility test in favor of a common law negligence analysis. One of the factors under the risk utility test is whether there is a safer alternative design. But as the Georgia Court of Appeals recognized, the risk utility test was jettisoned in Indiana in favor of a straightforward negligence approach. In arriving at that conclusion, the Georgia court cited to the Indiana Supreme Court's analysis in *TRW* and its explicit rejection of the Restatement (Third) of Torts: Products Liability § 2(b) (1997). *Bailey*, 721 N.E.2d at 374-75 (citing *TRW Vehicle Safety Systems v. Moore*, 936 N.E.2d at 209, n.2.).

While the road to *TRW* admittedly was rocky, and confusion still remains in this state, I believe that the Indiana Supreme Court has made itself clear. As a result, I agree with the Kaisers that proof of safer alternative design is not a *prima facie* requirement of their case. To hold otherwise would be in contradiction of the clear Indiana Supreme Court precedent established in *TRW*, to which I am bound.

That said, while the Kaisers are not required to prove safer alternative design, evidence of it is probative of the issue of the Ethicon's failure to use reasonable care under the circumstances in designing Prolift. *See TRW*, 936 N.E. 2d at 209-210. This brings us to the first two issues of Ethicon's *Daubert* motion. Ethicon argues that Dr. Elliott should be precluded from testifying that nonsynthetic mesh procedures, such a abdominal sacrocolpopexy, are a safer alternative for the surgical treatment of stress urinary incontinence. [DE 252 at 2-3; DE 280 at 7.] Ethicon argues that a proffered safer alternative design must be a product, not a procedure. I agree.

Back when negligent design defect claims were creatures of common law and proof of safer alternative design was required, a plaintiff was required "to show that another design not only could have prevented the injury but also was cost-effective under general negligence principles." *See Whitted*, 58 F.3d at 1206 (7th Cir. 1995) (quoting *Pries v. Honda Motor Co., Ltd.*, 31 F.3d 543, 546 (7th Cir. 1994). This standard, generally speaking, remains. In other words, if a plaintiff chooses to put on evidence of a safer alternative design to show that the manufacturer was negligent, they are also required to present evidence that their proposed safer alternative design is

economically feasible. *See, e.g., TRW*, 936 N.E. 2d at 209-210 (holding that there was sufficient evidence to support the jury's verdict for the plaintiff because, among other things, there was testimony that the defendant had been aware of the problem and that an alternative, safer design was both technologically and economically feasible).

At the risk of stating the obvious, design defect cases focus on the design of the *product* and if there was a feasible way to change the product to make it safer and avoid the injury at issue. I have found no cases in this jurisdiction, and the Parties have not pointed me to any, that consider a procedure or non-product as a relevant safer alternative design. That is likely because evidence of a procedure that could have been performed without the use of the product at issue does nothing to inform the jury on the issue of whether there was a safer alternative design *of the product*.

For these reasons, evidence of non-mesh treatment alternatives is inadmissible as proof of a "safer alternative design." However, that does not render this evidence inadmissible altogether. Certainly, it is admissible as part of the back story of this case, specifically as evidence of the options that were presented to Mrs. Kaiser to treat her pelvic organ prolapse and the history of the development of Prolift. The Parties do not contest this. Furthermore, the availability of non-mesh treatment alternatives also speaks to the whether Ethicon was negligent in its design of Prolift and may be considered in determining whether Ethicon exercised reasonable care under the circumstances in designing the product. So while non-mesh surgical treatment alternatives cannot be characterized as a "safer alternative design" by Dr. Elliott, it

amounts to much ado about nothing now that I have held that the Kaisers need not offer proof of a safer alternative design in the first place.

The final issue is whether Dr. Elliott should be precluded from testifying that other synthetic mesh devices offer safe alternatives. [DE 252 at 5.] Ethicon argues that Dr. Elliott should be precluded from testifying that other synthetic mesh devices were safer than Prolift on the basis that he does not believe that any safer alternatives exist because Dr. Elliott does not believe that any device containing mesh is practical, feasible, or reasonable. I disagree. The MDL Court found that Dr. Elliott is competent to testify about the alleged benefits of lighter weight/larger pore-size mesh. [DE 257-3 at 10.] The fact that he evidently does not believe that any such devices are safe does not preclude him from evaluating their safety on a comparative basis. His opinions on mesh, generally, speak to the weight to be given to his testimony on this point, not its admissibility. Ethicon will be free to cross-examine Dr. Elliott regarding his views of mesh devices generally and regarding any inconsistent testimony or statements he has given. Accordingly, this portion of Ethicon's motion is denied.

Conclusion

For the reasons discussed above, and at the oral argument held on November 28, 2017, Ethicon's Motion for Final Ruling as to Vladimir Iakovlev, M.D., DE 258, is **GRANTED** and Dr. Iakovlev is prohibited from testifying about his degradation bark theory. Furthermore, as I explained above, under Indiana law, the Plaintiffs are not *required* to prove that a safer alternative design to Prolift existed as an element of their

design defect claim. It is, however, *relevant* to the Plaintiffs' design defect claim and they may, therefore, offer evidence of safer alternative designs in support of that claim. Dr. Elliott's testimony regarding non-mesh surgical treatments is inadmissible as proof of a "safer alternative design." It is, however, admissible as it relates to Ethicon's alleged failure to exercise reasonable care under the circumstances in designing Prolift, generally. Finally, Dr. Elliott's testimony that other synthetic mesh devices offer safe alternatives is admissible. Ethicon's Motion for Final Ruling as to Daniel Elliott, M.D., DE 257, therefore, is **GRANTED IN PART AND DENIED IN PART** for the reasons stated in this Opinion and Order.

SO ORDERED.

ENTERED: February 7, 2018.

s/ Philip P. Simon
PHILIP P. SIMON, JUDGE
UNITED STATES DISTRICT COURT